REMARKS

Applicants amended claims 74, 78-80, 82-84, 88-89, 91-92, 96-99, 101-104, 108-112, 114-118, 122-125, and 127-139. Claims 74, 76-84, 86-92, 94-104, 106-118, and 120-139 are presented for examination.

Claim rejections – 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 74-129 under 35 U.S.C. § 112, first paragraph.[1]

While claims 74, 76-84, 86-92, 94-104, 106-118 and 110-129 are directed to articles without limitation to their methods of manufacture, the application provides a detailed description of exemplary processes that can be used in the preparation of the devices covered by these claims. (See, e.g., application at pages 17-24, Figs. 4A-4E and 5A-5E.) General features of such exemplary processes are disclosed at pages 17-21 with reference to Figs. 3A-3E and at pages 21-24 with reference to Figs. 5A-5E. The application discloses, for example, information relating to: the manner in which process temperature, longitudinal strain and internal pressure can depend upon each other (see, e.g., id., at page 18-19); appropriate process temperatures (see, e.g., id., at 19-22); appropriate longitudinal strains (see, e.g., id., at 20-21); and appropriate internal pressures (see, e.g., id., at 21-22).

Moreover, with respect to a polyamide having a tensile strength of at least about 21,000 pounds, in example H (application at page 28), an extruded sheath of Vestamid L2101 F Nylon 12 (a polyamide) was longitudinally stretched and blown under a longitudinal strain of 220% and an internal pressure of 142 psi. During longitudinal stretch blowing, the sheath material passed through an 18 inch oven at a temperature of about 63°C over a period of about 8.9 seconds. A 304L stainless steel hypotube having an outer diameter of about 0.0264 inch and an inner diameter of about 0.0200 inch was inserted inside the longitudinally stretched and blown sheath, and the sheath was bonded to the hypotube by heating to a temperature of about 113°C for at

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[1] Applicants cancelled claims 75, 85, 93, 105, and 119, so the rejection of these claims should be withdrawn.

least about 30 minutes. Five specimens sample H were tested, and the average tensile strength of specimens of sample H was 31,659 psi (application at page 26).

Further, regarding a polyamide having a hoop stress of at least about 3300 psi, in Example H, the average hoop stress of specimens is calculated to be 5,115 psi, using the outer and inner diameter values listed in Table II (id.) and the definition of hoop stress provided at page 11, lines 7 and 8 of the application.

In addition, with respect to a polyamide having a post buckle fracture tensile strength of at least about 6,500 psi, the application discloses numerous specific relevant examples. For example, in Example C (application at page 26), an extruded sheath of Vestamid L2101 F Nylon 12 (a polyamide) was longitudinally stretch-blown under a longitudinal strain of 220 % and an internal pressure of 208 psi. During longitudinal stretch-blowing, the sheath material passed through an 18 inch oven at a temperature of about 63°C over a period of about 8.9 seconds. A 304L stainless steel hypotube was inserted inside the longitudinally stretched and blown sheath, and the sheath was bonded to the hypotube by heating to a temperature of about 113°C for at least 30 minutes. The specimens of example C have a post buckle tensile strength of 13,642 psi (application at page 25-26, Table I), which is greater than 6500 psi as claimed. Further, the application discloses detailed processes for making examples D including a polyamide, Example E including a polyamide copolymer, Example F including a polyamide copolymer, and G including a polyamide copolymer, all of which have a post buckle average tensile strength of the hypotube sheaths greater than 6500 psi as claimed.

Regarding the term "load at break ratio" in claims 92-103, 111, and 117, while the definition of this term is not explicitly disclosed in the application, Applicants believe that, after reading the application, one skilled in the art would understand what is meant by this term. In addition to disclosing the "load at break ratio", Applicants disclose two other "ratio" parameters -- the "tensile strength ratio" and the "hoop stress ratio". (See, e.g., id. at page 24.) For the tensile strength ratio, Applicants disclose (see, e.g., id.):

> As used herein the tensile strength ratio of a catheter component material is determined by dividing the tensile strength of the material as a tube-shaped catheter component (according to one or more of the procedures described above)

> by the tensile strength of the material before being longitudinally or radially stretch-blown (e.g., as an extruded tube).

And, for the hoop stress ratio, Applicants disclose (see, e.g., id.):

> As used herein, the hoop stress ratio of a catheter component material is determined by dividing the hoop stress of the material as a tube-shaped catheter component (according to the procedure described above) by the hoop stress of the material before being longitudinally or radially stretch-blown (e.g., as an extruded tube).

Thus, it is apparent that one skilled in the art would understand that the load at break ratio of a catheter component material is determined by dividing the load at break of the material as a tube-shaped catheter component (according to one or more of the procedures described in the application) by the load at break of the material before being longitudinally or radially stretch-blown (e.g., as an extruded tube).

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 74, 76-84, 86-92, 94-104, 106-118, and 120-129 under 35 U.S.C. § 112, first paragraph.

Claim Rejections – 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 74, 80, 84, 89, 92, 99, 104, 112, 118, and 125 under U.S.C. 112, second paragraph, as being indefinite. Applicants amended these claims to obviate this rejection, so the rejection should be withdrawn.

Claim Rejections – 35 U.S.C. §102(b)

The Examiner rejected claims 84, 86, 88, 89, and 91 as anticipated by U.S. Patent No. 5,306,246 ("Sahatjian"). However, whereas Applicants amended these claims to cover articles that include a polyamide, Sahatjian does not disclose such articles. Rather, Sahatjian discloses blends of polyolefins (e.g., polyethylene, polypropylene, polybutylene and copolymers thereof) and polyesters for dilatation balloons, and discloses suitable polyolefins and polyesters for forming blends. (See, e.g., Sahatjian col. 3, lines 4-7, lines 14-15, and lines 37-43). While

Sahatjian does disclose that known methods for blending incompatible polymers such as polyolefins and condensation polymers (e.g., polyamides, polyesters, or polycarbonates) can be found in U.S. Patent No. 4,444,817 (see, e.g., id., col. 3, lines 48-63), Sahatjian does not disclose or suggest forming his dilation balloon out of a polyamide. Instead, Sahatjian's reference to polyamides is with respect to prior known methods of processing various incompatible polymers, and how those methods can apparently be used to blend Sahatjian's polymers. Accordingly, Sahatjian does not disclose the subject matter covered by claims 84, 86, 88, 89, and 91, and Applicants therefore request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 74, 76-78, 80-82, 106, 107, 113, 118, 120-123, and 125-128 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,860,998 ("Robinson"). But, Applicants amended these claims to cover articles including polyamides, and Robinson does not disclose such articles. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 103

The Examiner rejected claims 79, 83, 124, and 129 under 35 U.S.C. § 103(a) as being unpatentable over Robinson in view of Sahatjian.

Claims 79, 83, 124, and 129 cover articles including polyamides. As discussed above, Robinson does not disclose such articles. Sahatjian does not cure Robinson's deficiencies, at least because, like Robinson, Sahatjian does not disclose an article including a polyamide. Neither Robinson nor Sahatjian, alone or in combination, discloses or suggests the articles covered by claims 79, 83, 124 and 129. There is no suggestion to combine these references to provide such articles, and, even if the references were combined, the result would not be the articles covered by these claims. Thus, Applicants request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 87 and 90 under 35 U.S.C. 103(a) as being unpatentable over Sahatjian in view of U.S. 6,110,142 ("Pinchuk"). Claims 87 and 90 cover medical devices including a polyamide having a hoop stress of at least about 3300 psi. As discussed above, Sahatjian does not disclose articles including a polyamide.

Further, there is no suggestion to modify Sahatjian to provide such articles. Rather, Sahatjian discloses that a blend of a polyester and a polyolefin can have advantageous properties of softness, high hoop stress, and high burst pressures. (See, e.g., Sahatjian, col. 3, lines 4-10). Sahatjian further discloses that a polyolefin can contribute to properties of improved softness or compliance such that the balloon may yield when challenged by the wall of a body lumen, and that the blend of a polyolefin and polyethylene terephthalate does not greatly reduce the strength of the balloon. (See, e.g., Sahatjian, col. 4, lines 54-59). After reading this, one skilled in the art would not have been motivated to modify Sahatjian with the teachings of Pinchuk to provide the articles covered by claims 87 and 90. As a result, Applicants request reconsideration and withdrawal of this rejection.

Applicants believe the application is in condition for allowance, which action is requested.

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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